

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 20-19V**

PAMELA STEWART,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES

Respondent.

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Filed: March 5, 2025

Timothy R. McCarthy, Nutt Law Office, Louisville, KY, for Petitioner.

Tyler King, U.S. Department of Justice, Washington D.C., for Respondent.

RULING ON ENTITLEMENT¹

On January 2, 2020, Pamela Stewart (“Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petitioner alleges that an influenza vaccine she received on October 5, 2018, caused “adverse effects,” including pain, swelling, and an abscess. *See generally* Petition. The vaccine she received was administered by a Kentucky mobile vaccination entity that was later determined to have exercised inadequate safety control over its vaccines, resulting in numerous vaccinated individuals experiencing comparable abscess injuries.

Respondent opposes Petitioner's claim, arguing that the Act's “severity” requirement cannot be met. After a careful review of the entirety of the parties’ submissions, I find that

¹ “Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*”

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

Petitioner has preponderantly established that her injury persisted at least six months post-vaccination. *See* 42 U.S.C. § 300aa-11(c)(1)(D). Therefore, Petitioner is entitled to compensation.

I. Relevant Procedural History

This matter was initiated at the same time as a number of related petitions brought by similarly-situated claimants.³ Respondent raised an overarching objection to these claims – that they did not fall within the ambit of the Program because the alleged vaccine-related abscess was directly attributable to third-party negligence. The parties consented to resolution of entitlement in one “test case,” the results of which could then be applied to the related cases. On April 25, 2024, I ruled in favor of the petitioner in the test case, finding that the administration of the influenza vaccine had caused him to experience a right shoulder skin abscess associated with a bacterial infection. *See Silvers v. Sec’y of Health & Hum. Servs.*, No. 20-1V, 2024 WL 2799285 (Fed. Cl. Spec. Mstr. Apr. 25, 2024).

On September 17, 2024, I held a telephonic status conference (under the auspices of the test case matter) to discuss resolution of the remaining cases. I proposed at that time that Respondent evaluate the related matters and determine if entitlement could be conceded in light of my ruling, or if facts specific to the remaining cases required different treatment. On October 10, 2024, the parties filed a joint status report in the four remaining cases, announcing that Petitioner did not intend to file additional evidence relevant to the issue of six-month severity and requesting deadlines for Rule 4(c) reports. I subsequently ordered the parties to file Rule 4(c) Reports in the related matters by November 15, 2024.

On November 13, 2024, Respondent filed a Rule 4(c) Report in this action, arguing that Petitioner was not entitled to compensation because of her failure to satisfy the Act’s six-month severity requirement. (ECF No. 32). In response, I ordered Petitioner to file a brief showing cause why the petition should not be dismissed for inability to meet the severity requirement. Order to Show Cause, dated Nov. 14, 2024 (ECF No. 33). On December 30, 2024, Petitioner filed her response to the Order. Petitioner’s Brief (ECF No. 34) (“Br.”). On January 30, 2025, Respondent filed his opposition. Respondent’s Opposition (ECF No. 36) (“Opp.”). The matter is now ripe for decision.

II. Factual Background

Petitioner was born on July 7, 1963, and was 55 years old at the time of vaccination. Ex. 1. She received the flu vaccine in her left arm on October 5, 2018, and it was administered by the

³ *See generally Silvers v. Secretary of Health and Human Services* (No. 20-1V), *Stastny v. Secretary of Health and Human Services* (No. 20-22V), *Atkins v. Secretary of Health and Human Services* (No. 20-333V), *Williams v. Secretary of Health and Human Services* (No. 20-1048V), and *Williams v. Secretary of Health and Human Services* (No. 20-1120V).

same mobile vaccination entity discussed in *Silvers*. Ex. 3 at 1; Ex. 2. On January 9, 2019, Petitioner presented to her primary care provider (“PCP”), Dr. Anna Fisher, complaining of a reaction to the October 2018 vaccination. Ex. 3 at 1. In the history of present illness section of the record of this visit, Dr. Fisher wrote that Petitioner had experienced tenderness and warmth at the site after she was vaccinated. *Id.* As of the January 9th appointment, the site was still “quite tender.” *Id.* Dr. Fisher diagnosed Petitioner with an acute infection, likely an abscess, and referred her to a general surgeon for drainage. *Id.*

On January 11, 2019, Petitioner had an appointment with the surgeon, Dr. Gregory Strothman. Ex. 4 at 22. She represented that she developed pain and swelling in her arm two months after vaccination and explained that these symptoms had progressively worsened. *Id.* She described the pain as throbbing and intermittent. *Id.* Dr. Strothman drained the abscess and took cultures from the body fluid. *Id.* at 24. One of the cultures tested positive for mycobacterium fortuitum. *Id.* at 27.

On February 24, 2019 (now approximately four and a half months post-vaccination), Petitioner was examined by infectious disease specialist Dr. Makhawadee Pongruangporn at the request of her PCP. Ex. 5 at 5. Dr. Pongruangporn noted that Petitioner no longer had an abscess, but the tingling and arm swelling had persisted. *Id.* Dr. Pongruangporn determined that Petitioner likely had a chronic infection and recommended a culture. *Id.* at 6. He noted that he would start Petitioner on treatment depending on the results of the culture. *Id.* Dr. Pongruangporn attempted to aspirate (drain) the wound twice, without success. *Id.* He ordered Petitioner to continue levofloxacin and Bactrim for three months. *Id.* at 7.

On April 25, 2019 (now seven months post-vaccination), Petitioner had a follow-up with Dr. Pongruangporn. Ex. 5 at 33. Although Petitioner no longer had an abscess on her arm, Dr. Pongruangporn did note the presence of a small scar. *Id.* He also noted that Petitioner was experiencing “some systemic symptoms with fatigue” and hypersensitivity at the injection site. *Id.* Petitioner again followed up with Dr. Pongruangporn on July 23, 2019, nine months post-vaccination. *Id.* at 60. By this appointment, Petitioner was feeling “much better.” *Id.* Her pain had subsided, and she was no longer fatigued. *Id.*

III. Parties’ Arguments

Petitioner

Petitioner claims that she experienced residual effects and/or complications for more than six months after the administration of the vaccine. Br. at 4. In support, she points to Dr. Pongruangporn’s note from April 25, 2019, which states that Petitioner was experiencing “some systemic symptoms of fatigue.” Ex. 5 at 33. The notes also state that Petitioner had hypersensitivity

at the injection site. *Id.* Petitioner claims that this proves she was still having active symptoms over six months after her vaccination. Br. at 4. As the medical records indicate, Petitioner’s symptoms got better sometime between her April 25 and July 23, 2019 appointments. *Id.*

Respondent argues that Petitioner cannot meet the six-month severity requirement because she no longer had an active “abscess” on her arm by the July 2019 visit. Br. at 5. But Petitioner points out that the Act does not require Petitioner to have an ongoing surgical lesion or abscess in order to meet the severity requirement. *Id.* Rather, the requirement simply states that a petitioner must suffer residual effects and complications beyond the six-month mark, and Petitioner argues there is “absolutely no doubt” that she was suffering well past six months as evidenced by pain, hypersensitivity, and a scar at the injection site. *Id.* at 5-6.

To support this, Petitioner cites *Wright v. Sec’y of Health and Hum. Servs.*, 22 F.4th 999, 1005 (Fed. Cir. 2022), which states, “[r]esidual suggests something remaining or left behind from a vaccine injury...An effect that is ‘residual’ or ‘left behind’ is one that never goes away and recurs after the original illness.” Br. at 6. Petitioner argues that continued fatigue, hypersensitivity, pain, tingling, swelling, and scarring undoubtedly meet the definition of “suffered” and “complications.” *Id.* Accordingly, a simple reading of the notes proves that Petitioner can meet the severity requirement. *Id.* at 7.

Respondent

Respondent maintains that Petitioner has not satisfied the statutory “severity” requirement for her alleged vaccine injury. Opp. at 1. While Petitioner attempts to allege that her injury persisted for more than six months in her affidavit, this is not corroborated by the medical records. *Id.* at 2. Thus, when Petitioner visited Dr. Pongruangporn on April 25, 2019, he noted that she no longer had an abscess. Ex. 5 at 33. And is not clear from the record that the “small scar” was related to Petitioner’s flu vaccine. Opp. at 2. Respondent concludes that the medical records “unequivocally indicate” that Petitioner’s shoulder abscess had resolved approximately four and a half months post-vaccination. *Id.* She is, therefore, not entitled to an award of compensation. *Id.* at 3.

ANALYSIS

The petitioner carries the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is “documentation demonstrating severity – generally, that the petitioner “suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” Section 11(c)(1)(D)(i)9; *see also Black v. Sec’y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the “potential petitioner”

must not only make a prima facie case, but clear a jurisdictional threshold, by “submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case”), *aff’d*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec’y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

In addition, I note the legal standards applicable to proving the various elements of a Vaccine Act claim. The Act prohibits finding a petition requirement satisfied “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” §13(a)(1). Medical records must be considered, *see* Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). However, the Federal Circuit has recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

It is thus certainly the case that factual matters required to prove elements of a Vaccine Act claim may be established by a mix of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing §12(d)(3); Vaccine Rule 8), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

In this case, the medical records objectively preponderate in favor of a finding that Petitioner’s injury likely persisted for more than six months post-vaccination. Petitioner was clearly suffering from adverse effects of the abscess at her February 24, 2019 appointment, as evidenced by her complaints of tingling and swelling and Dr. Pongruangporn’s unsuccessful attempts to aspirate her wound. Ex. 5 at 5-6. Indeed, Petitioner was ordered to continue her prescribed medications at this time. *Id.* at 7. By her April 25, 2019 appointment, which occurred *seven months* post-vaccination (and thus after the six-month severity “deadline”), Petitioner was continuing to suffer from systemic symptoms with fatigue and hypersensitivity at the injection site, even though the abscess itself had somewhat resolved. Ex. 5 at 33.

Petitioner also has offered her own contentions relevant to this severity finding. *See* Ex. 2. As the Vaccine Act makes clear, “a special master or court may not make such a finding based on

the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1); *see also Lett v. Sec’y of Health and Hum. Servs.*, 39 Fed. Cl. 259, 260 (1997) (“[u]ltimately, the petitioner must substantiate the occurrence of a compensable, vaccine-related injury with independent evidence”). But these fact contentions are corroborated by the medical records, which establish Petitioner’s claims of lingering symptoms past the six-month mark. And Petitioner seems to have fully recovered sometime between her April appointment and her July appointment – over six months after her October vaccination. All of this evidence allows for a conclusion that Petitioner’s injury can satisfy the Act’s severity requirement.

CONCLUSION

For these reasons, I find that Petitioner has provided preponderant evidence sufficient to meet the severity requirement, and is otherwise entitled to compensation. The parties shall file a status report on or before **April 11, 2025**, setting forth their progress in resolving damages in this case (which, consistent with other comparable abscess cases, should be quite modest).

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master